APPENDIX A

Movant Dr. Persaud herein presents the following additional transcript references illustrating the improper opinion testimony given at trial by the Government's numerous physician witnesses which were presented as "lay" witnesses.

Dr. Persaud moves this Court for permission to submit further transcript references in support of the arguments set forth in his Memorandum in Support of his Motion to Vacate and Set Aside Judgment of Conviction Pursuant to 28 United States Code Section 2255, at any future hearing or briefing opportunity.

Additional References from Dr. John Coletta's Trial Testimony

While being asked about the "correct" level of stenosis, thus opining that Dr. Persaud's analysis and determinations regarding patient [RE] were incorrect, Dr. Coletta testified:

Q. And in your review of [RE]'s IVUS image and the angio films, what was the percentage of stenosis that you found [RE] to have?
A. In the left main artery, you are referring to?
Q. Correct.
A. Less than 30 percent.

(John Coletta Transcript (Doc# 177, Page ID 2119-2120))

Additional References from Dr. Barry George's Trial Testimony

In the following lengthy excerpt from Dr. Persaud's trial, at the prompting of the Government, Dr. George explained in detail some of his analysis and critique of Dr. Persaud's medical practices, judgment, and decisions to insert stents, on a patient-by-patient basis. Clearly, Dr. George's testimony is tantamount to "expert" testimony, presented to the jury, as the trier of

fact, for the purpose of explaining, *inter alia.*, scientific concepts, accepted practices, and specific conclusions regarding Dr. Persaud's testing and treatment of his patients.

Dr. George testified with "authority" regarding many topics, including: the American College of Cardiology guidelines relative to stenosis percentages, when "intervention" by the cardiologist is "appropriate", and when testing is justified, and what kind(s) of testing are acceptable.

Q. You referenced the 70 percent number. This jury has heard about the American College of Cardiology, and I'm sure you are familiar with the ACC?
A. Yes, I am.
Q. And does the American College of Cardiology have guidelines regarding the percentage of stenosis and when intervention is appropriate?
A. They do have guidelines. In the -- as a general rule, if the blockage is greater than 70 percent, most guidelines feel that using or considering coronary stenting in this day and age is appropriate. In the range of 50 to 70 percent, and some people it may be 40 to 70 percent, it is called "may be appropriate," but usually you have to have some sort of adjunctive information or supplementary information to justify placing stents in those 40 to 70 percent or 50 to 70 percent, depending on who you read, stage.

(Barry George Transcript (Doc# 186, Page ID 3682))

Dr. George was also asked to give his opinion about the usefulness of Nuclear Stress Test imagery. Dr. George testified:

Q. Dr. George, does a nuclear scan image in this format provide you any additional useful information?
A. For the most part, no.
Q. Why is that?

A. It -- the, when you see nuclear scans, it's -- you have to have really a very good copy of the image of the scans, not a Xerox copy, or the actual scan itself that was immediately post processed in order to accurately determine whether there's, as we call it in laypersons' terms, shadows or cold spots on regions of the heart muscle. And these were, in my opinion, not adequate to do that.

(Barry George Transcript (Doc# 186, Page ID 3694-3695))

A. This basically is a case-by-case analysis and conclusion of my independent assessment of the angiogram and the intravascular ultrasound, and then my opinion of the appropriateness of stenting.
Q. And this is, if we can go to Page 2 of Government's Exhibit 211, please, this is a two-page document, is that correct, Dr. George?
A. Yes.
Q. If we can go back to Page 1 of 211, please, Dr. George, can you kind of walk us through here what each column represents and explanation of what you wrote in these columns? Let's just start with the first patient, patient number 169103.
A. Okay. This is -- that was the patient's medical record number in the St. John Lakeshore system, I believe. And then it was the patient's name, patient's last name. And then the next column is my interpretation of the images on intravascular ultrasound and angiogram. And then the far right-hand column is my opinion of the -- what was done, whether it was appropriate or inappropriate.
Q. Thank you. So we see "RCA 40% by IVUS and angio." Does that mean that you found the IVUS image to depict 40% stenosis in the RCA?
A. That's correct.
Q. And that you also found the angiogram to be 40% stenosis in the RCA?
A. That's correct.
Q. Okay. And then your conclusion that it was inappropriate stenting of the mid RCA?
A. Correct.

Q. And if we can zoom back out, please. And then as -- we will not review every case here, but as we go down, let's go to one, two, three -- the fifth line down, 232190 Bowman, you indicated "RCA 30% by angio, IVUS of guide catheter, LIMA unindicated." What did you mean by that?

A. In this patient's analysis of the intravascular ultrasound and of the angiogram, my impression was that the narrowing in the right coronary artery -- that's one of the three major vessels that supplies your heart -- was 30%. The "IVUS of guide only" means that the images that I had to review showed only an intravascular ultrasound picture of the inside of the guiding catheter. What a guiding catheter is is a tube, a hollow tube that is kind of the gateway or the conduit into the body and into the coronary arteries from the skin surface. It's the little hollow tube we use to put the little guide wire in the balloon and the stent through that tube to get to the arteries from the outside of the body. The images that I had on this particular patient that were ultrasound images were ultrasound images of the inside of this hollow tube or guiding catheter, and I did not see any pictures of the artery itself.

Q. Does that give you any kind of clinical assessment? Is there any clinical value to IVUS of the inside of the guide catheter?

A. None whatsoever.

Q. And as an aside, in your review of these IVUS images, did you find anything in the IVUS films to indicate that there was technical problems with the IVUS machine itself?

A. No, the images I would say probably for the most part were adequate images that could be interpreted. In other words, we had good enough picture. We didn't have what we call echo dropout or ultrasound dropout, so the images that were recorded were satisfactory for interpretation.

Q. Looking back at Government's Exhibit 211, you wrote, "LIMA unindicated."
What does that mean?

A. This patient probably on angiogram had an internal mammary artery. That's the blood vessel off the inside of your chest wall. It is an artery, and it is commonly used when bypass surgery is done to -- it's taken off the inside of the chest wall and basically

hooked to the main artery in the front of the heart, the LAD. It's quite commonly used by heart surgeons for -- it's a wonderful bypass conduit. What I was implying here is that I did not see any upstream blockage in the artery on the angiogram that would have suggested that that surgery was needed previously in this patient.

Q. And then you indicated again in the far right column, "Inappropriate stenting of proximal RCA," is that correct?

A. Correct.

* * *

Q. Dr. George, this jury's heard a lot about referrals for bypass surgery, and I'm going to try to limit my questions here to you to that extent. I'm assuming you have made, in your practice, referrals to cardiothoracic surgeons, is that correct?

A. Yes, I do.

Q. And in your experience and your knowledge of working with cardiothoracic surgeons, do they know how to read IVUS?

A. It would be a highly unusual cardiothoracic surgeon that knew how to read intravascular ultrasound of coronary arteries, in my experience.

* * *

Q. And in this case that you looked at, [RE] with the 30% by angio, would that 30% by angio of the left main be something that would be indicative of bypass surgery in and of itself?

A. Absolutely not.

* * *

Q. And you highlighted the importance of accurately and honestly documenting the IVUS readings in order to justify placing a stent, is that correct?

A. That is correct.

Q. And then like we spoke about a few moments ago, it's important to accurately document the IVUS readings in the cases of referral for bypass surgery, is that also
correct?

A. Yes.

Q. So then turning to the last sentence of this second paragraph on Page 2 of Government's Exhibit 210, what was your conclusion regarding Dr. Persaud's use of IVUS?
A. That based on the 30 cases that I reviewed, I could only lead to the conclusion that Dr. Persaud had not had adequate training in the interpretation of intravascular ultrasound.

* * *

Q. Now, if we can go to the third full paragraph on Page 2 of 210, Dr. George, what were your findings regarding the second and third questions posed to you from St. John Medical Center, the improper use and indications for IVUS and the improper IVUS image interpretation?
A. Well, in regards to the execution and interpretation of the intravascular ultrasound, I felt that it fell -- it was substandard, it fell below the standard of care in -- it certainly is not the standard of care to ultrasound the inside of the guiding catheter and recording it.
Everybody knows what the -- what size the guiding catheter is and, you know, for the most part the companies are pretty good and there's no blockage in the guiding catheter, so that struck me as terribly peculiar. Despite all that, in all these interventional procedures that Dr. Persaud did of these 30 cases that stents were placed, there was a satisfactory outcome with the stent.
Q. In fact, you say the interventional procedures achieved excellent outcomes, so was Dr. Persaud technically skilled at his ability to perform the stenting procedures?
A. Absolutely.
Q. So in your assessment, Dr. Persaud knew what he was doing?
A. Oh, it was very clear to me that Dr. Persaud is a skilled technician when it comes to performing angioplasty and placing coronary stents.

Q. If we can go then to the last three paragraphs on Page 2 of 210. Dr. George, can you tell the jury then the rest of your findings with respect to your review of these 30 cases, starting with your analysis regarding referrals for bypass surgery?
A. Well, it was my concern that Dr. Persaud was not skilled in the interpretation of intravascular ultrasound to the point where he could use this in his clinical decision-making process to determine whether or not patients needed coronary stents or needed coronary artery bypass surgery, in essence.
Q. And then did you ultimately conclude that based on Dr. Persaud's recommendations, there were unnecessary procedures, including stenting and bypass surgery, performed?
A. Yes, I did.

* * *

Q. After you did this review of 30 patients, were you later contacted by St. John Medical Center to do some additional review of patients of Dr. Persaud's cases?
A. Yes.

Q. If we can pull up Government's Exhibit 212, please. And highlight the top written portion. Dr. George, is this a summary of the second batch of 21 cases that you reviewed for St. John Medical Center?
A. Yes.

Q. And it says, "IVUS cases, Dr. Persaud." That's pretty self-explanatory. Can you briefly tell the jury what -- explain your two columns here.
A. I recall that I was asked to review a second batch of patients or set of patients with basically focusing my energies on whether or not the appropriate use of stenting was -- and intravascular ultrasound was used by Dr. Persaud in this second batch of patients, if you may. So really, the question was -- that was to be answered was, "Hey, look at the IVUS images, look at the coronary angiograms; tell us whether you think that it was appropriate what Dr. Persaud did."

* * *

Q. Why is it so concerning to you that a patient who did not have indications for intervention for a stent ends up getting a stent?
A. Well, you know, to the layperson it's like, well, geez, or to perhaps the outside observer, oh, okay, so you got a stent in your coronary artery and it looks great, you got less than five percent blockage there, what's the big deal, okay, the patient's fine. That's not really true, okay. You now have a piece of metal in your coronary artery, and that thing is a potential liability for the rest of your life. It could also be a potential asset for the rest of your life. But the fact of the matter remains that many patients will still have to be on cardiac medications and blood thinners at least for a year and maybe for the rest of their life, and with its potential issues with causing other types of bleeding. So when you place a stent in a person's coronary artery, it can be a liability or it can be an asset, so that's the reason why, as I've mentioned before, you better have a proof of purchase coupon before you go putting this piece of hardware in there. Now, the cool thing about this is -- and I can't help myself to teach -- we will soon have stents that disappear, they will be absorbed, so you put them in the artery and within two years they're gone. And the artery gets back to its normal biology and cellular physiology business. So that's very exciting stuff. But if you have a piece of metal in your artery, like I say, it can be liability, it can be an asset, so it's a serious matter.

(Barry George Transcript (Doc# 186, Page ID 3697- 3714))

In a continuing criticism of Dr. Persaud's medical decisions to test and treat his cardiac patients, Dr. George testified:

Q. Still looking at Government's Exhibit 211, if we can zoom out and go back to [RE], patient 213866 that we'd spoken about a little bit ago, Dr. George, what if this patient had no angina and no chest pain, would that change your interpretation or conclusion that IVUS may have been appropriate based on a 30% visual?

A. Well, the -- if the patient had no angina or no chest pain and had no abnormal stress test, then I'm -- it begs the question what are you doing in the cath lab to begin with, first of all. Secondly, that if you have what appears to be a 30% blockage and there is no other ancillary clinical or imaging evidence that there is a problem, then IVUS is inappropriate here.

(Barry George Transcript (Doc# 186, Page ID 3723))

Additional References from Dr. John Letcher's Trial Testimony

In a further effort to diminish Dr. Persaud's level of skill and technique relative to performing a stenting procedure, Dr. Letcher, testifying as an "expert" stated the following opinion regarding Dr. Persaud's stenting of a patient who had had a bypass surgery:

Q. All right. And so what happened? Even though the bypass was functioning, what is it that you found that Dr. Persaud did?
A. Put a stent in a native vessel proximal to the bypass.

Q. All right. And so when you're describing proximal to the bypass, help us understand that that actually means then. So the bypass is still functioning but he went back to the original vessel that was being bypassed and placed a stent there?
A. That's correct.
Q. Okay. What's wrong with that?
A. It may be correct in certain situations where there's proximal jeopardized vessels. It may be incorrect if there's no proximal jeopardized vessels, meaning lack of ischemia in that distribution, and potentially you could long-term cause jeopardy to both the stented area and the bypassed area, secondary competitive flow.
Q. So with all that explanation, what you're describing is that by placing the stent in there, it actually creates a risk of harm?
A. Potentially.
Q. All right. But at least placing the stent itself is a separately billable event in this case?
A. Correct.

Q. All right. And you found that with two of the patients. If we can go then to Page 2 then of Government's Exhibit 273 – I'm sorry – Page 1. And as we go down your summary list here of the different patients that you were analyzing there, do you see a [JE]?
A. Yes.
Q. And is he one of those two patients that you found that issue with?
A. Yes.
Q. All right. And staying on that same page, if we go to the bottom of the page, there's a finding in the [RR] where you say "Inappropriate RCA stent," and if we go to her specific page which is Government's Exhibit 273, Page 44, it's the second-to-last page in that packet, and as we focus about two-thirds of the way in terms of anatomy, RCA, we have "Mild proximal less than 30%." So is it the case then with patient [RR], you found that the area that was stented was the RCA and that you actually saw less than 30% blockage there?
A. Yes.

(John Letcher Transcript (Doc# 187, Page ID 3916-3918))

Additional References from Dr. Joseph Cacchione's Trial Testimony

In what can only be described as a very technical, very scientific analysis which absolutely warranted a Rule 702 inquiry, the following excerpt of testimony includes Dr. Cacchione's explanation of his analysis regarding the procedures performed by Dr. Persaud. Dr. Cacchione was asked about his opinions and the conclusions he **and his team** made during his investigation. Dr. Cacchione explained his categorization of Dr. Persaud's medical procedures into at least four separate categories, and the rationale behind such categorization.

The following excerpt is the Dr. Cacchione's complex assessment and overall severe scrutiny of Dr. Persaud's work:

Q. To get these other things that you're looking at. All right. So if we go to Page 4, now, of Government's Exhibit 240, so you mentioned on the previous page that it's only 16 or the 80 you could say were appropriate. How many did you find to be in that "Uncertain" area?
A. So there were 27 cases that were in the "Uncertain" area, or 34%.
Q. All right. So 20% in the "Appropriate" category and you've got 34% now in this "Uncertain" category that you can't place in the "Appropriate" or in the "Inappropriate"?
A. Correct.
Q. All right. And then it look like you have two different charts to break down that "Uncertain" category. The first of which, correct me if I'm wrong, but you had nine of those 27 "Uncertains" in the 50 to 69% range?
A. So when you look at the appropriate use criteria, they are the angiographic thresholds and then which in this case was in the borderline area, and then you add in the clinical things we talked about, the symptoms, the stress test results, other high risk features, anti-anginal medications, so then those were applied to those borderline lesions and that's what made that group fall out is that they lacked the clinical criteria, they lacked the documentation of the clinical criteria for meeting the appropriate use criteria.
Q. And then the second of the charts that you have there for the "Uncertain" area, you have 18 patients of the 27 then in "Uncertain" where you actually have the greater than or equal to 70 percent stenosis, is that correct?
A. Yes
Q. So why are they in that category still of "Uncertain"?

A. Because they didn't meet the clinical criteria that we spoke of on the borderline ones the same. This area, I will say this area, if there is an area of controversy in interventional cardiology, this would be that area of those people that have a type blockage or a blockage more than 70 percent that don't necessarily meet the clinical criteria. And so this is probably the gray zone for interventional cardiologists where there is probably more variability amongst cardiologists across the country, but in this area, in our applying –- we don't do this any differently for Dr. Persaud than we do for Joe Cacchione. We apply these criteria across the board to everybody the same. Very straightforward, objective way to do that.
Q. So these are ones where you have the 70 percent or above, but you were lacking other reasons then to go ahead and stent the person. It's not one you got the magic number, that wasn't enough to be able to say, "I could put in a stent"?
A. Right.
Q. All right. So other things you were looking for were the symptoms, and that that was one of the issues that you had an issue with in these patients?
A. Right
Q. And another might be the amount of –- the number of anti-anginal medication classes that were being used?
A. Yes.
Q. And stress test results was another example?
A. Yes.
Q. That you had some of these that had normal stress test results or at least low risk stress test results?
A. Yes.
Q. All right. And then lastly on this page, how many of the eighty cases did you find to be inappropriate based on the criteria that you applied?
A. Thirty-seven.
Q. All right. And so as a percentage of the whole population of all 2011 stents that Dr. Persaud placed, how many of them then did you find to be inappropriate?
A. 46%.
Q. There's a chart then at the bottom of that page that kind of breaks them down a little bit. Can you tell us why those 37 cases were found to be inappropriate?

A. In 35 of them, it was due to the fact that there was a less than a 50 percent stenosis, and one there was a blood vessel that was totally blocked but did not meet the criteria based on the clinical parameters. And then the one other patient had a bypass surgery previously. All the bypasses were open and it didn't meet the clinical criteria for doing a stent procedure on the vessel that was being supplied by one of those vein bypasses that were open.

(Joseph Cacchione (Doc# 187, Page ID 4009-4013))

A particularly noteworthy example of Dr. Cacchione (and his team's) critique, patient by patient, of Dr. Persaud's purported lack of skill in determining percentiles of stenosis and in his decisions to place stents. Dr. Cacchione's testimony included a comparison of Dr. Persaud's assessments of stenosis to Dr. Cacchione's "team's" assessments of stenosis. This expert testimony was seriously damaging to Dr. Persaud. As the Government's apparent expert witness, Dr. Cacchione further gave gratuitous testimony that the differences he found in stenosis percentiles was not possibly due to "interobserver variability", a concept brought up during Dr. Persaud's trial which accounts for some subjectivity (10%) in obtaining readings or results. In a somewhat lengthy exchange, Dr. Cacchione testified:

Q. Okay. So in this first example then with [CD], your team assesses the lesion to be 40 to 50%. Dr. Persaud had it at 75 to 80. And then there's also a column for quantitative coronary analysis, QCA?
A. Yes.

(Joseph Cacchione Transcript (Doc# 187, Page ID 4015))

Q. And with respect to [MG], Dr. Persaud noted 80 to 90 in his record, and your team visually saw what?
A. Thirty.
Q. And the computer analysis, the QCA came up with what number?
A. Forty-four.

Q. If we could stay on the same page and go to the bottom, there's an indication for a patient named [AK] with a date of service of March 24th of 2011.
A. Yes.
Q. And what did Dr. Persaud assess her stenosis level to be?
A. Seventy percent.
Q. And what was your team's visual read on that?
A. Twenty percent.
Q. And the computer came up with?
A. Thirty-five percent.
Q. So again this is not something that you can attribute to interobserver variability?
A. Correct.
Q. All right. If we can go to Page 2 now of Government's Exhibit 241, as you look at that page, Dr. Cacchione, if I can draw your attention to the third line, there's a patient [SH], and what's the indication in the records you had available as to what Dr. Persaud found the level of stenosis to be in her mid RCA?
A. Seventy percent.
Q. And your team visually saw what?
A. Thirty.
Q. And the computer came up with?
A. Thirty-seven percent.
Q. Again this is not interobserver variability?
A. Correct.
Q. This is an inappropriate stent?
A. Does not –- yes.

(Joseph Cacchione Transcript (Doc# 187, Page ID 4018-4020))

Q. And in this case Dr. Persaud noted that it was the RCA was the target lesion area that he was focusing on?
A. Yes.
Q. And the he assessed that area to be what level of blockage?
A. Seventy-one percent.
Q. And your team saw it as?
A. Thirty percent.

(Joseph Cacchione Transcript (Doc# 187, Page ID 4023))

Q. All right. And Dr. Persaud has noted that as being 72% blockage?
A. Yes.

Q. All right. And your team visually saw that as what?
A. Thirty-five percent.

(Joseph Cacchione Transcript (Doc# 187, Page ID 4027))

Q. In this case you were looking at a mid RCA stent, place in the mid RCA?
A. Yes.
Q. And Dr. Persaud assessed that as what?
A. Sixty to 70 percent.

Q. And your team saw it visually as?
A. Thirty percent.
Q. And the computer determined that it was what percent blockage?
A. Twenty-six percent.
Q. So same rationale, this is too low, this is an inappropriate blockage to stent?
A. Yes.

(Joseph Cacchione Transcript (Doc# 187, Page ID 4027-4028))

Q. Can you tell us what you found when you examined cases of Dr. Persaud using IVUS in those 80 cases?
A. Yes. So I assume people know what IVUS is?
Q. Yes.
A. So there in the 37 cases, there were 15 cases that had IVUS. In all of those cased, our assessment of the IVUS was that the IVUS was interpreted incorrectly by the operator and that the degree of stenosis was being overestimated or over – overcalled by the operator. And it’s just –- it’s a fact that it was –- they were interpreted incorrectly and that they were – they were incorrect.
Q. All right. So in those 37 now out of the 80 that you found to be in the “Inappropriate” category, in that pool of 37, you found he had used IVUS in 15 of those, correct?
A. Correct.
Q. And all 15 uses were misinterpreted?
A. Correct.

Q. And did you find any evidence of Dr. Persaud actually measuring inside the guide catheter?
A. We found him measuring really it was artifact as his percent stenosis so –- and that had to be –- I mean, it was just they were being done incorrectly.

(Joseph Cacchione Transcript (Doc# 187, Page ID 4030-4031))

Q. All right. In this second batch, can you tell us about the analysis that was employed by your team then to look at the second batch?
A. So there were 67 cases. 35 were determined to be "Appropriate." 18 were in the "May be appropriate" category. And 14 were in the "Rarely appropriate" category. And the respective percentages were 52 for the "Appropriate" and 27 for the "May be appropriate" and 21 for the "Rarely appropriate" category.

(Joseph Cacchione Transcript (Doc# 187, Page ID 4034-4035))